REMARKS

Claims 21-25 are canceled herein. Claims 16 and 20 are amended to correct a translation error. Support for the amendment to claims 16 and 20 can be found in the specification on page 15, lines 15-19 as discussed herein below. Support for new claims 26-31 can be found on page 6, line 15 to page 8, line 5 and page 13, lines 22 to 24 of the specification. Upon entry of the amendment, claims 1, 3-20 and 26-31 will be all the claims pending in the application. Entry of the Amendment is respectfully requested.

I. Restriction/Election Requirement

On page 2 of the Office Action, the Examiner indicates that claims 21-25 are considered to be drawn to a non-elected invention under the doctrine of election by original presentation. According to the Examiner, claims 21-25 are drawn to a method of masking taste which is independent and distinct from the original claims of the application. Specifically the Examiner states that new method claims 21-25 comprise different method steps and different modes of operation from original method claims 19 and 20.

Claims 21-25 are canceled herein without prejudice or disclaimer. Applicants reserve the right to file a divisional application directed to the subject matter thereof.

II. Response to Claim Rejections Under 35 U.S.C. § 112, 1st paragraph

Claims 1 and 3-20 are rejected under 35 U.S.C. § 112 first paragraph, allegedly because the specification does not reasonably provide enablement for any drug with unpleasant tastes other than the drug compounds listed in the specification from page 6, line 15 to page 8, line 5, for the reasons of record. Additionally, the Examiner listed the eight factors to be considered to

determine whether any necessary experimentation is undue, but does not appear to address the factors. The Examiner also states that the arguments made in the Amendment filed on December 6, 2001, were not persuasive.

Applicants respectfully traverse the rejection. First, Applicants respectfully submit that the Examiner's reasons for maintaining the rejection are not entirely clear. The Examiner appears to repeat the same reasons without specifically addressing the arguments set forth in the amendment filed on December 6, 2001. For instance, on pages 5-6 of the Office Action the Examiner states that Applicants' arguments were found to be unpersuasive but does not give a specific reason as to why. Instead the Examiner quotes the portion of the specification referred to by Applicants and then states, "[t]he compounds with unpleasant taste are including various classes of compounds herein. Therefore, one of skill in the art *could* (emphasis added) ascertain which specific compounds from the disclosed classes of compounds would be useful in the claimed invention without undue experimentation," which appears to be an admission of enablement on the Examiner's part.

Further, in response to Applicants' arguments that the rejection was improperly based on only one factor for determining enablement, the Examiner simply states that the argument was not considered persuasive for the reasons set forth above. However, as previously discussed the Examiner does not appear to do any more than list the factors to be considered with respect to enablement.

It appears as if the Examiner may intend to suggest that the recited portion of the specification referring to words and phrases such as "especially", "include" and "the like" does

not provide sufficient enablement for the claimed invention. However, Applicants submit that these terms are not recited in the claims and therefore it is improper to read limitations into the claims from the specification.

Applicants reiterate that the relevant inquiry is whether the invention is sufficiently disclosed so that one of ordinary skill in the art would be able to practice the invention without undue experimentation. *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916); *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). The test of enablement is whether one of ordinary skill in the art could make or use the claimed invention from the disclosure coupled with information known in the art, without undue experimentation. *United States v. Telectronics, Inc.* 857 F.2d 778, 785 (Fed. Cir. 1988). Additionally, the fact that experimentation may be necessary does not make it undue if such experimentation is routine within the art. *In re Angstadt*, 537 F.2d 498, 504 (CCPA 1976).

In view thereof, Applicants submit that the claims recite "a drug having at least one basic group within its structure, thereby rendering an unpleasant taste". One of ordinary skill in the art can look to Applicants' specification for guidance and find a description of what the terms in the claims mean as well as exemplary compounds within the scope of the claimed invention. In addition, based upon the disclosure at page 5, lines 5-14 of the specification, coupled with the level of skill in the art and the information available to the skilled artisan, one of ordinary skill in the art would be able to select a drug with an unpleasant taste based upon a common structural feature as described in the specification. As such, the specification is enabling for the claims.

In regard to the Examiner's reliance on the alleged unpredictability in the art of structural differences in compounds, Applicants submit that based upon the nature of the

invention of masking the unpleasant taste of a drug compound; the state of the prior art and the level of one of ordinary skill in the art; the level of predictability in the art of predicting unpleasant tastes of a chemical compound based upon common structural characteristics; the amount of direction provided by the inventor; the existence of exemplary drugs in the specification; and the fact that any experimentation to practice the present invention would be considered as routine experimentation in view of the disclosure, Applicants respectfully submit that the claimed invention is sufficiently enabled such that one of ordinary skill in the art would be able to practice the claimed invention without undue experimentation.

III. Response to Claim Rejections Under 35 U.S.C. § 112, 2nd Paragraph

Claims 1 and 3-20 were rejected under 35 U.S.C. § 112, 2nd paragraph as allegedly being indefinite for the reasons of record with respect to the terms, "unpleasant taste," "bitter taste," and "corrective agent." The rejection of the term "taking ability" was withdrawn in view of the amendments made to the claims."

Applicants respectfully traverse the rejection. Specifically, the Examiner's focus in determining whether the claims are definite in compliance with 35 U.S.C. § 112, second paragraph should be whether the claims set out the claimed subject matter with a reasonable degree of clarity and particularity in light of (1) the content of the specification; (2) the teachings of the prior art; and (3) the claim interpretation that would be given by one of ordinary skill in the art.

Applicants have set forth in the specification definitions of the terms "unpleasant taste" and "bitter taste" as well as a standard for ascertaining the degree of bitterness, and thereby unpleasant taste, in the sensory tests provided on pages 21-25. Thus in view of the arguments

previously made, Applicants respectfully submit that when read in light of the specification one of ordinary skill in the art would be able to ascertain the full scope of the claimed invention.

In regard to the term "corrective agent" the Examiner states that the arguments made in the Amendment filed on December 6, 2001, are not persuasive because there is no single common function or property among the examples of corrective agents listed in the specification.

Applicants have amended the specification and claims 16 and 20 by replacing the term "corrective agent" and "correctives" with "flavoring agent" and "flavoring agents", respectively, to correct an error in translation. The term "corrective agent" was incorrectly translated and is meant to refer to flavoring agents, i.e., substances having the function of giving flavor. The compounds listed on page 15, lines 15-17, as correctives are examples of flavoring agents as commonly known to those of ordinary skill in the pharmaceutical art. For example, as disclosed in the present specification, L-menthol is known to impart a refreshing or cool oral sensation. Mentha, which is also listed in the present specification, is known to those of ordinary skill in the pharmaceutical art to provide a minty taste (e.g., spearmint and peppermint). In view thereof Applicants respectfully request withdrawal of the rejection.

IV. Response to Claim Rejections Under 35 U.S.C. § 102

Claims 1, 3-7, 9, 12-14 and 16-18 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Pearmain for the reasons of record.

Applicants respectfully traverse the rejection. Applicants submit that Pearmain discloses a technique directed to a palatable granule comprising cimetidine which is prepared by granulating cimetidine with a particular amount of a particular polymethacrylate copolymer. In this technique, polymethacrylate is used as an essential element for providing palatability.

According to the present invention, however, complicated operations such as the granulation of a drug with a polymethacrylate copolymer need not be required. Also, Applicants note that the claims recite a taste masking oral administration preparation *consisting essentially of* a drug having at least one basic group in its structure, thereby rendering an unpleasant taste, a sugar alcohol having a heat of dissolution of –20 cal/g or less and a pH adjusting agent. Therefore, the present invention is distinguished from Pearmain which requires additional ingredients such as the polymethacrylate polymer.

With respect to claim 31 Applicants submit that the new claim is distinguished over Pearmain for at least the same reasons discussed above and further in view of the recited amount of the sugar alcohol added of 40 to 70% by weight based on the total weight of the pharmaceutical preparation. In this connection, the amount of the sugar alcohol (Sorbitol) added in Example 3 of Pearmain is 680 mg/tablet and the total amount of the tablet preparation is 2065 to 2085 mg. Therefore, the amount (ratio) of the sugar alcohol added is calculated as 32.3 to 32.6% based on the total weight of the tablet preparation, which is outside of the recited range. Accordingly, Applicants respectfully request withdrawal of the rejection.

V. Response to Claim Rejections Under 35 U.S.C. § 103

Claims 8, 10-11, 15, 19 and 20 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Pearmain in view of Hoshino for the reasons of record. Further, the Examiner did not find the arguments made in the Amendment filed on December 6, 2001, to be persuasive. Specifically, the Examiner states that Hoshino is not limited to improving discomfort such as roughness or dustiness in the mouth. Further, the Examiner asserts that since sugar alcohols are known to be sweet, it would have reasonably been expected that the use of a sugar alcohol as

disclosed by Hoshino would improve taste as well as roughness or dustiness. Thus, it is the Examiner's position that the combination of Pearmain and Hoshino renders the claims obvious because a better palatable oral administration would have reasonably been expected based upon the teachings of employing a sugar alcohol, pH adjusting agent and sweetener. Additionally, the Examiner states that the argument regarding the dissolution of the active ingredient in the oral cavity before swallowing is not persuasive because both Pearmain and Hoshino teach the compositions can be formulated into chewable tablets.

Applicants respectfully traverse the rejection. As previously mentioned, Hoshino relates to a technique of improving the intrabuccal sensations (discomfort such as roughness or dustiness) characteristic of chewable tablets containing a gastrointestinal drug (as is apparent from the Examples, especially sucralfate). The improved effect is intrabuccal sensations but not taste.

In the first instance, sucralfate does not have a basic group in its structure and it is a medicament having no taste. As a reference material, we are enclosing the portion relevant to sucralfate of the Japanese Pharmacopoeia. In the item "properties" of sucralfate in the Japanese Pharmacopeia as shown in the attached paper, it is described that "this product is a white powder and it does not have a smell or a taste".

Accordingly, sucralfate is a substance having no (unpleasant) taste. Namely, the features of Hoshino are not to improve the unpleasant tastes of drugs to such a degree that the unpleasant tastes are reduced or completely undetectable, regarding the taking of oral administration preparations of drugs having unpleasant tastes which are dissolved completely or partially in the oral cavity before swallowing then, as in the present invention.

On the other hand, the present invention has been achieved to improve the unpleasant tastes

of drugs to such a degree that the unpleasant tastes are reduced or completely undetectable, regarding the taking of oral administration preparations of drugs having unpleasant tastes which have a possibility of the drug contacting directly with the oral cavity, e.g., powders, granules and tablets, in which film coating and the like is not carried out, and tablets and granules which are quickly dissolved or disintegrated in the oral cavity.

The present invention is not directed to the case that they are made into pharmaceutical preparations as capsules, sugar coated tablets, film coated tablets and the like dosage forms in order to mask unpleasant tastes of drugs at the time of their taking.

That is, the present invention aims at improving the unpleasant tastes of drugs to such a degree that the unpleasant tastes are reduced or completely undetectable, regarding the taking of oral administration preparations of drugs having unpleasant tastes which are dissolved completely or partially in the oral cavity before swallowing them

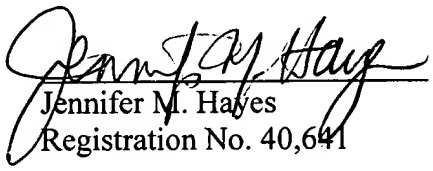
As described above, the skilled person would not have been motivated to combine the teachings of Pearmain (directed to an entirely different method of reducing the unpleasant taste of drugs) and Hoshino (directed to the improvement of only the intrabuccal sensations characteristic to chewable tablets) with a reasonable expectation of arriving at Applicants' claimed invention. Accordingly, Applicants respectfully request withdrawal of the rejection.

VI. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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APPENDIX

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION:

The specification is changed as follows:

On page 14, please replace the second full paragraph:

The oral administration preparation of the invention may contain generally used various pharmaceutical additives in such amounts that they do not spoil the effects of the invention. Examples of such pharmaceutical additives include excipients, disintegrators, binders, lubricants, coloring agents, flavors, sweeteners, ~~correctives~~ flavoring agents and the like.

On page 15, please replace the `first full paragraph:

Examples of the sweeteners include aspartame, stevia, thaumatin, saccharin sodium, dipotassium glycyrrhizinate and the like. Aspartame is particularly preferable among these sweeteners, because it has an effect to remove salty taste generated by the addition of a sodium salt as a pH adjusting agent. Aspartame is added in an amount of from 0.1 to 2% by weight, preferably from 0.05 to 1% by weight, more preferably from 0.1 to 0.5% by weight based on the total weight of the pharmaceutical preparation. Examples of the ~~corrective~~ flavoring agents include L-menthol, camphor, mentha, monosodium L-glutamate monohydrate, dibasic sodium inosinate, magnesium chloride and the like. Among them L-menthol is particularly desirable, because it exerts a refreshing feeling and further increases the bitterness-improving effect. L-Menthol is added in an amount of from 0.01 to 2% by weight, preferably from 0.05 to 1% by weight, more preferably from 0.1 to 0.5% by weight, based on the total weight of the preparation.

IN THE CLAIMS:

Claims 21-25 are canceled.

The claims are amended as follows:

16. (Twice Amended) The oral administration preparation according to claim 1, ~~w~~herein it further contains a sweetener or a ~~corrective~~ flavoring agent.

20. (Twice Amended) The method of masking the taste of an oral administration preparation according to claim 19, wherein a sweetener and/or a ~~corrective~~ flavoring agent is further included.

Claims 26-31 are added as new claims.